K092140

AUG 21 2009

Attachment B

Summary of Safety and Effectiveness
Prepared in accordance with 21 CFR Part 807.92(c)

g

GE Healthcare

General Electric Company
3000 N. Grandview Blvd., Waukesha, WI 53188

Section a):

1. Submitter: GE Healthcare
3000 N. Grandview Blvd., W450
Waukesha, WI 53188
USA

Contact Person: James T. Turner, MS, RAC
USA Premarket RA Leader
Telephone: 262-544-3359; Fax: 414-908-9225

Date Prepared: July 14, 2009

2. Device Name: GE Vivid-i and Vivid q Diagnostic Ultrasound System
Ultrasonic Pulsed Doppler Imaging System, 21 CFR 892.1550, 90-IYN
Ultrasonic Pulsed Echo Imaging System, 21 CFR 892.1560, 90-IYO
Diagnostic Ultrasonic Transducer, 21 CFR 892.1570, 90-ITX

3. Marketed Device: GE Vivid i and Vivid q Diagnostic Ultrasound System K082374, currently in commercial distribution.

4. Device Description: The GE Vivid-i and Vivid-q is compact and portable diagnostic ultrasound system with integrated keyboard, fold-up LCD type display and interchangeable electronic-array transducers. It has an overall size approximately 36 cm wide, 31.5 cm deep and 6 cm high in transport configuration and provides digital acquisition, processing and display capability. The user interface includes a computer keyboard, an intuitive layout of specialized controls, color GUI display and Doppler audio.

5. Indications for Use: The device is intended for use by a qualified physician for ultrasound evaluation of Fetal; Abdominal; Pediatric; Small Organ (breast, testes, thyroid); Neonatal Cephalic; Adult Cephalic; Cardiac (adult and pediatric); Peripheral Vascular; Musculo-skeletal Conventional and Superficial; Urology (including prostate); Transesophageal; Transrectal; Transvaginal; Intraoperative (abdominal, thoracic, and vascular), Intra-cardiac and Intra-luminal.

6. Comparison with Predicate Device: The modified GE Vivid-i and Vivid q BT10 is of a comparable type and substantially equivalent to the currently marketed GE Vivid-i and Vivid q BT09. It is a compact and readily portable unit having the same design, construction, and materials; is comparable in key safety and effectiveness features. It has the same intended uses as the predicate device and additional software features are identical to that of other cleared GE Ultrasound systems.

Section b):

1. Non-clinical Tests: The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness as well as thermal, electrical and mechanical safety, and has been found to conform with applicable medical device safety standards.

2. Clinical Tests: None required.

3. Conclusion: Intended uses and other key features are consistent with traditional clinical practice, FDA guidelines, and established methods of patient examination. The design and development process of the manufacturer conforms with 21 CFR 820, ISO 9001 and ISO13485 quality systems. The device conforms to applicable medical device safety standards and compliance is verified through independent evaluation with ongoing factory surveillance. Diagnostic ultrasound has accumulated a long history of safe and effective performance. Therefore, it is the opinion of GE Medical Systems that the GE Vivid i and Vivid q BT10 Diagnostic Ultrasound is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

AUG 21 2009

GE Medical Systems Israel, Ultrasound, Ltd.
% Mr. James T. Turner, MS, RAC
USA Premarket RA Leader
GE Healthcare, QARA Regions-America
3000 N. Grandview Blvd.
WAUKESHA WI 53188

Re: K092140
Trade/Device Name: GE Vivid i and Vivid q Diagnostic Ultrasound Systems
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: August 5, 2009
Received: August 6, 2009

Mr. Turner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the GE Vivid i and Vivid q Diagnostic Ultrasound Systems, as described in your premarket notification:

Transducer Model Number

8C-RS
4C-RS
SoundStar 3D 10F
AcuNav™ 8F

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Joshua Nipper at (301) 796-6524.

Sincerely yours,

for Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

K092140

Diagnostic Ultrasound Indications for Use Form

GE Vivid i and Vivid q Diagnostic Ultrasound System

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes[*]	Harmonic Imaging	Coded Pulse[◆]	Other
Ophthalmic											
Fetal	P	P	P	P	P	P	P	P	P	P	
Abdominal[1]	P	P	P	P	P	P	P	P	P	P	
Pediatric	P	P	P	P	P	P	P	P	P	P	
Small Organ (specify)[2]	P	P	P		P	P	P	P	P	P	
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	
Cardiac[3]	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular	P	P	P	P	P	P	P	P	P	P	
Musculo-skeletal Conventional	P	P	P		P	P	P	P	P	P	
Musculo-skeletal Superficial	P	P	P		P	P	P	P	P	P	
Other[4]	P	P	P		P	P	P	P	P	P	
Exam Type, Means of Access											
Transesophageal	P	P	P	P	P	P		P	P		
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)[5]	P	P	P	P	P		P	P	P		
Intraoperative Neurological											
Intracardiac and Intraluminal	P	P	P	P	P	P		P	P		
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes Renal.
[2] Small organ includes breast, testes, thyroid.
[3] Cardiac is Adult and Pediatric.
[4] Other use includes Urology.
[5] Intraoperative includes abdominal, thoracic (cardiac), and vascular (PV).
[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.
[◆] Coded Pulse includes Coded Octave Imaging (COI), and Coded Phase Inversion (CPI).

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices

510(k) Number K092140

Diagnostic Ultrasound Indications for Use Form

GE Vivid i/q with 8C-RS Transducer

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes[*]	Harmonic Imaging	Coded Pulse[†]	Other
Ophthalmic											
Fetal											
Abdominal	P	P	P		P	P	P	P	P	P	
Pediatric	P	P	P		P	P	P	P	P	P	
Small Organ (specify)[1]	P	P	P		P	P	P	P	P	P	
Neonatal Cephalic	P	P	P		P	P	P	P	P	P	
Adult Cephalic											
Cardiac	N	N	N		N	N	N	N	N	N	
Peripheral Vascular	P	P	P		P	P	P	P	P	P	
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intracardiac and Intraluminal											
Laparoscopic											

N = new indication (previously cleared by FDA on GE LOGIQ Book Ultrasound K032477); P = previously cleared by FDA on Vivid i (K033139) and Vivid i/q (K082374); E = added under Appendix E

Notes: [1] Small organ includes breast, testes, thyroid.

[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.

[†] Coded Pulse includes Coded Octave Imaging (COI), and Coded Phase Inversion (CPI).

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092140

K092140

Diagnostic Ultrasound Indications for Use Form
GE Vivid i/q with 4C-RS Transducer

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse'	Other
Ophthalmic											
Fetal	P	P	P		P	P	P	P	P	P	
Abdominal[1]	P	P	P		P	P	P	P	P	P	
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	N	N	N		N	N	N	N	N	N	
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other[2]	P	P	P		P	P	P	P	P	P	
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intracardiac and Intraluminal											
Laparoscopic											

N = new indication (previously cleared by FDA on Vivid 7 K051449); P = previously cleared by FDA on Vivid i (K061525) and Vivid i/q (K082374); E = added under Appendix E

Notes: **[1]** Abdominal includes Renal;
[2] Other use includes Urology.
[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.
[']Coded Pulse includes Coded Octave Imaging (COI), and Coded Phase Inversion (CPI).

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092140

Diagnostic Ultrasound Indications for Use Form

GE Vivid i/q with SoundStar 3D 10F Transducer

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal											
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [1]	N	N	N	N	N	N		N	N		
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intracardiac and Intraluminal	N	N	N	N	N	N		N	N		
Laparoscopic											

N = new indication (previously cleared as a stand alone medical device K070242 by Biosense Webster, Inc.);
P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Cardiac is Adult and Pediatric.
[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092140

K092140

Diagnostic Ultrasound Indications for Use Form

GE Vivid i/q with AcuNav™ 8F Transducer

Intended Use: Ultrasound imaging, measurement and analysis of the human body as follows:

Clinical Application *Anatomy/Region of Interest*	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal											
Abdominal											
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [1]	N	N	N	N	N	N		N	N		
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Other											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transuretheral											
Intraoperative (specify)											
Intraoperative Neurological											
Intracardiac and Intraluminal	N	N	N	N	N	N		N	N		
Laparoscopic											

N = new indication (previously cleared as a stand alone medical device K071234 by Siemens Medical Solutions);
P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Cardiac is Adult and Pediatric.
[*] Combined modes are B/M, B/PWD, B/CWD, B/Color/PWD, B/Amplitude/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription User (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092140